SECTION 1: Identification

Contact information

Astellas US LLC
2375 Waterview Drive
Northbrook, IL 60062
Tel.: 800-888-7704
www.us.astellas.com

Emergency telephone number
800-727-7003 Medical Communications

Product identifier
Avacincaptad Pegol

Synonyms
Avacincaptad Pegol Sodium, X01B, ARC1905, Zimura®

Trade name
Izervay™

Chemical family
PEGylated oligonucleotide

Recommended uses and restrictions
Pharmaceutical research, manufacture of clinical drug product, and clinical use.

Note
This SDS is written to address potential worker health and safety issues associated with the handling of the active pharmaceutical ingredient. The pharmacological, toxicological, and ecological properties of this substance have not been fully characterized. This SDS will be updated as more data become available.

SECTION 2: Hazard(s) identification

Classification of the substance or mixture
Not classified

Label elements

GHS Hazard pictograms
Not applicable

GHS Signal word
Not applicable

GHS Hazard statements
Not applicable

GHS Precautionary statements
Not applicable

Other hazards
Avacincaptad pegol is a PEGylated single strand RNA aptamer that is a specific inhibitor of the complement system, a key pathway in initiating an inflammatory and immune response. Adverse effects (e.g., eye discomfort) were associated with intravitreol injection of the drug product. Systemic effects on complement pathways are not expected following avacincaptad pegol exposure.

Note
This substance does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it has not yet been fully tested and is pharmacologically active.

SECTION 3: Composition/Information on ingredients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS number</th>
<th>EINECS/ELINCS#</th>
<th>Amount</th>
<th>GHS classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avacincaptad Pegol</td>
<td>1491144-00-3</td>
<td>N/A</td>
<td>= 100 %</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

(Main constituent)

Note
Full text of classification categories and H statements: see section 16

SECTION 4: First-aid measures

Description of first aid measures
**Immediate medical attention and special treatment, if necessary**

Inhalation: No.
Skin contact: Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Eye contact: If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Ingestion: If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

**Most Important Symptoms/Effects**
Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

**Expected Symptoms/Effects, Acute and Delayed**
See Sections 2 and 11

### SECTION 5: Fire-fighting measures

**Suitable (and unsuitable) extinguishing media**

**Suitable extinguishing media**
Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

**Specific hazards arising from the chemical**
No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen and other fluorine-, and phosphorous-containing compounds.

**Fire hazard**
No information identified.

**Explosion hazard**
No information identified. High concentrations of finely divided organic particles can explode if ignited.

**Special protective equipment and precautions for fire-fighters**

**Firefighting instructions**
In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

### SECTION 6: Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

**Protective equipment**
If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.

**Emergency procedures**
Do not breathe dust.

**Environmental precautions**
Do not empty into drains. Avoid release to the environment.

**Methods and material for containment and cleaning up**

**Methods for cleaning up**
DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice with an appropriate solvent (see section 9).

**Other information**
Dispose of materials or solid residues at an authorized site.

**Reference to other sections**
See Sections 8 and 13 for more information.

### SECTION 7: Handling and storage

**Precautions for safe handling**
Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Do not breathe dust.

**Conditions for safe storage, including any incompatibilities**

**Storage conditions**
Store in a closed container.

**Storage temperature**
-20 ± 5 °C

**Specific end use(s)**
Pharmaceuticals.

### SECTION 8: Exposure controls/personal protection

<table>
<thead>
<tr>
<th>Name</th>
<th>Issuer</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avacincaptad Pegol</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Appropriate engineering controls

Control exposures to below the OEL (for the active ingredient(s) if available). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. If handling bulk powder: No open handling; control systems such as ventilated enclosures are required. Use of clean-in-place systems is recommended.

Respiratory protection

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Eye protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin and body protection

Wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and degowning practices.

Other protective measures

Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

Environmental exposure controls

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 9: Physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Lyophilized powder / cake</td>
</tr>
<tr>
<td>Formula</td>
<td>PEGylated Fluoro-modified oligonucleotide</td>
</tr>
<tr>
<td>Molecular mass</td>
<td>Proprietary</td>
</tr>
<tr>
<td>Color</td>
<td>White to off-white, white to yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Fundamental burning velocity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosion limits</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

Conditions to avoid

(See section 7: Handling and Storage).

Incompatible materials

No data available

Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.
SECTION 11: Toxicological information

Likely routes of exposure
As a large molecular weight compound, it is not likely to be systemically absorbed through inhalation, skin contact, or ingestion.

Toxicological information

Acute toxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avacincaptad Pegol</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Sensitization</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>Rat, IV LOAEL: 260 mg/kg Effects: Hematological changes, serum chemistry changes, lymphoid atrophy, thymic necrosis, bone marrow hypocellularity. Mortality at ≥540 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monkey, IV LOAEL: 86.2 mg/kg Effects: Mild hematological and serum chemistry changes.</td>
<td></td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>Rat (7-day), IV LOAEL: 367 mg/kg Effects: Lowered body weight; mild hematological and serum chemistry changes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monkey, IV LOAEL: 141 mg/kg Effects: Hematological and serum chemistry changes, changes to coagulation profile parameters, macrophage vacuolization (liver, spleen, lymph nodes, bone marrow, kidney, lungs, choroid plexus, adrenal gland). Mortality at 1410 mg/kg.</td>
<td></td>
</tr>
</tbody>
</table>

Reproductive toxicity
No data available

Developmental toxicity
No data available

Genotoxicity

In vitro:
Bacterial reverse mutation assay (e.g. Ames test): negative
Chromosomal aberration assay (peripheral human lymphocytes): negative

In vivo:
Mouse micronucleus assay: negative

Carcinogenicity
No data available

Aspiration hazard
No data available

Experience with humans
See “Section 2 - Other Hazards”.

SECTION 12: Ecological information

Toxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avacincaptad Pegol</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Persistence and degradability</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Bioaccumulative potential</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Mobility in soil</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Results of PBT assessment</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Other adverse effects</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Note</td>
<td>No special precautions are needed.</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 13: Disposal considerations

Waste treatment methods
Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g. appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g. appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14: Transport information

Transport
Based on the available data, this substance is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN number
None assigned.

UN proper shipping name
None assigned.

Transport hazard class(es) (DOT)
None assigned.

Packing group
None assigned.
Marine pollutant: Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.

Special transport precautions: No special precautions required.

Transport in bulk according to Annex II of Marpol and the IBC Code: Not applicable

### SECTION 15: Regulatory information

| Safety, health and environmental regulations/legislation specific for the substance or mixture | This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information. |
| Chemical safety assessment | No chemical safety assessment has been carried out |
| TSCA | Drugs are exempt from TSCA. |
| SARA Section 313 - Emission Reporting | This substance or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372. |

| California Proposition 65 | California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm |

| Additional information | No additional information available |

### SECTION 16: Other information

| Data sources | Information from published literature and internal company data. |
| Abbreviations and acronyms | ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System |

| Issue date | 08 February 2024 |
| Current revision | 5.0 |

**Disclaimer**

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.